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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/515,283	02/29/2000	Nora Aghassi	P-6335.01CIP	1899

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Daniel D Chapman
Jackson Walker LLP
112 E Pecan
Suite 2100
San Antonio, TX 78205

EXAMINER

GRUN, JAMES LESLIE

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 06/21/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/515,283

Applicant(s)

AGHASSI et al.

Examiner
James L. Grun, Ph.D.

Art Unit
1641



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 Apr 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 45-57 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 45-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Technology Center 1600, Group 1640, Art Unit 1641.

The amendment filed 19 April 2002 is acknowledged and has been entered. Claims 1-44 have been cancelled. The new claims filed 19 April 2002 as claims 145-157 were renumbered under 37 CFR § 1.126 as claims 45-57, respectively. Claims 45-57 remain in the case.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 45-47 and 49-51 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, and which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with that as claimed.

Applicant discloses (see e.g. page 10) that a number of buffering agents are useful in the invention, including citric acid, and that the choice of an appropriate buffer is dependent upon the desired pH range, the buffer choice allowing altering the pH of the composition of the invention from about 1 to 11. Further applicant discloses preferred pH ranges for compositions of the invention comprising SIMPLE GREEN®, for example between pH 5 and 10 (page 4) when no

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buffer is specified, or a pH range of 5.96 to 6.04 when the SIMPLE GREEN® composition also comprises citrate explicitly or implicitly as the buffer of choice (see e.g. pages 11 or 13). Citrate has known pKa values which determine the effective ranges of its buffering capacity. Thus, applicant does not describe and one would not be able, absent further description and guidance from applicant, to buffer a composition comprising SIMPLE GREEN® over the full range of pH values as instantly claimed incorporating citrate as the buffer of choice.

Claims 45-47 and 49-55 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 45 and 47, "the pH" lacks antecedent basis.

In claims 45-47 and 49-51, "the antigenicity" lacks antecedent basis.

In claim 47, the claimed subject matter would be clearer as to what composition is intended if --to remove the composition-- or --to remove excess composition-- was recited at line 5. The relationship of the contacting the tissue step to the removing the slide step is not clear because it is not clear that the slide is immersed or otherwise contacted in a fashion amenable to removal.

In claims 49-51, "The method of claim [46]" lacks antecedent basis. It is believed that claim 47 may have been intended. However, if such was intended, note that a multiple dependent claim cannot depend from any other multiple dependent claim.

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In claims 50-51, "the surfactant" lacks antecedent basis in claim 46 and it is not clear what is being further limited, even if the claim depended from claim 47, because the components of a specific composition (SIMPLE GREEN®) are claimed.

In claims 51, 53, and 55, improper Markush language is used to claim the members of the group. The alternatives "is at least one of...or", or "selected from...or", or "selected from the group consisting of...and" are acceptable.

In claim 51, the claimed subject matter would be clearer if --at least one of a cationic, anionic, amphoteric, or nonionic surfactant-- was recited.

。 In claim 52, "tissue activating agent" should be --the tissue activating agent-- for proper antecedent support.

In claim 54, the relationship of a "buffering agent" to the previously recited "buffer" is not clear.

Claims 45-49, 51, 52, 54, 55, and 57 are rejected under 35 U.S.C. § 102(b) as being anticipated by Cell Marque Corporation ("Immuno Pathology 1998 Products & Reference Guide") in light of the instant disclosure and Kennedy (U.S. Patent No. 5,856,289) for reasons of record in the prior rejection of the similar subject matter of claims 17-21, 23, 27-35, 37, and 41-44.

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Claims 48-57 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the combined teachings of Hazelbag et al (J. Histochem. Cytochem. 43: 429-437, 1995), Shi et al (J. Histochem. Cytochem. 43: 193-201, 1995), and Yörükoğlu et al (Appl. Immunohistochem. 5: 71, 1997) for reasons of record in the prior rejection of the similar subject matter of claims 1, 3, 5, 6, 8-10, and 12-44.

Claims 48-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hazelbag et al, Shi et al, and Yörükoğlu et al, and, if necessary, further in view of either of Norton et al (J. Pathol. 173: 371-9, 1994) or Miller et al (Applied Immunohistochem. 3: 190-3, 1995) for reasons of record in the prior rejection of the similar subject matter of claims 1, 3, 5, 6, 8-10, and 12-44.

Note that the instant claims have not been accorded the benefit of the filing date of the parent application, USSN 08/957,098, because the parent application does not provide written description support or enablement for the invention of the scope as instantly claimed. Among other things, the parent application does not describe or suggest a chelator in the composition or, as set forth above for the instant application, a composition comprising SIMPLE GREEN® over the full range of pH values as instantly claimed incorporating citrate as the buffer of choice.

Applicant's arguments filed 19 April 2002 have been fully considered but they are not deemed to be persuasive. Notwithstanding applicant's assertions, and those in the declaration of Dr. Lacey under 37 CFR § 1.132, to the contrary, the subject matter as instantly claimed is not fully supported by the disclosure of parent application, USSN 08/957,098, for the reasons set forth previously in this Office action, incorporated herein, and thus the instant claims have not

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been accorded the benefit of the 1997 filing date of the parent application as argued by applicant. Thus, the declaration under 37 CFR § 1.131 was also not found persuasive because the reference of Yörükoğlu et al qualifies as prior art under 35 U.S.C. § 102(b) for the subject matter as instantly claimed as a whole.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A SHORTENED STATUTORY PERIOD FOR REPLY TO THIS FINAL ACTION IS SET TO EXPIRE **THREE MONTHS** FROM THE MAILING DATE OF THIS ACTION. IN THE EVENT A FIRST REPLY IS FILED WITHIN **TWO MONTHS** OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE **THREE-MONTH** SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR REPLY EXPIRE LATER THAN **SIX MONTHS** FROM THE MAILING DATE OF THIS FINAL ACTION.

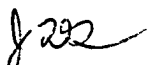
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (703) 308-3980. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (703) 305-3399.

The phone numbers for official facsimile transmitted communications to TC 1600, Group 1640, are (703) 872-9306, or (703) 305-3014, or (703) 308-4242. Official After Final communications, only, can be facsimile transmitted to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. The above inquiries, or requests to supply missing elements from Office communications, can also be directed to the TC 1600 Customer Service Office at phone numbers (703) 308-0197 or (703) 308-0198.


James L. Grun, Ph.D.
June 19, 2002


CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1888/641